Kure Sai Vyshnavi

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Date of Birth	22 Sep 1993
Languages known	Telugu, English, Hindi

EMPLOYMENT HISTORY

EMPLOYER	DESIGNATION	DEPARTMENT	DURATION
Mankind Pharma Ltd. Manesar, Haryana, India	Research Associate	Clinical Research & Biopharmaceutics	Apr 2019 - Present
Aurigene Discovery Technologies	Clinical executive	Clinical Research	Feb 2018- Feb 2019
PPD	Project assistant -Central	Remote Site Monitoring	Sep 2015- Jan 2018

Job Responsibilities

Research Associate-Department of Clinical Research & Biopharmaceutics
Mankind Research Centre ***April 2019- Till present***

- Provide support to plan and design allocated BA/BE & clinical studies
  Review clinical portion of study protocols.
- Coordinate with internal working groups to facilitate documents for seeking study approval and BENOC/T License applications
- Coordinate with CROs in study start up activities like IP Management, preparing study schedule, Subject recruitment and sample processing facilities etc. before initiating the study.
- To maintain contracts and agreements of different vendors & study files of ongoing and completed projects.
- Assist in maintaining financial aspects of ongoing studies. Verifying the invoices against contract and processing it for the payments.
- Literature review and assimilation on the latest trends in clinical trial and bioequivalence.
- Review clinical portion of study reports for accuracy, consistency and compliance.

Clinical executive –Clinical Development Department ***Feb 2018 – Feb 2019***
Aurigene Discovery technologies, Electronic city, Bangalore.

- Coordinate with the clinical project team for distribution, retrieval and review of documents required for clinical trial initiation and eTMF maintenance
- Evaluating Site feasibility for registration of new sites into the Trial.

- Sending Notifications to DCGI regarding new sites & SAE Notifications.
- Maintenance of different trackers (Patient Recruitment Tracker, SAE Tracker, Vendor Tracker, Payments Tracker etc.)
- Support clinical trial operational plans ensuring that clinical trials are conducted in a timely fashion and compliant with SOPs, GCP, regulatory guidelines, company goals, and budgets.
- Coordinating with different vendors for timely deliverables and to check if they have met the timelines.
- Take part in SIV Visit as a sponsor representative & performs Monitoring visit report review.
- Design of monthly newsletters to the sites.
- Take part in CRO study update meetings to follow-up recruitment status on the study.
- Verification of EDC for Timely entry of data for sites.

Project Assistant – C ***Sep 2015 – Jan 2018***
PPD (Pharmaceutical Product development) Bangalore.

- Review regulatory documents for proper content in accordance with FDA, ICH/GCPs, PPD and Client Company appropriate SOPs prior to submission to the Project Manager, central IRB, Regulatory Affairs and/or the client.
- Post and distribute CTMS project specific guidance document to project team.
- Creation of study documents, reports and Coordinate in the eTMF setup Maintenance and closeout.
- Oversee the execution and dissemination of study related information, including project tracking updates to clients, clinical study teams and other PPD departments.
- Finalize the table of content for all study files (Central, Internal, Country, and Investigator), develop and distribute filing guidelines to clinical team.
- Perform file reviews and log outstanding issues in project related tracking tools.
- Submission of documents to Central and Internal files and update in CTMS.
- Develop and maintain assigned data points within the CTMS database according to the established conventions and tools for the project, within specified timelines.
- Assist in the creation of study specific documents and plans (e.g. Communication Plan, Monitoring
- Plan, etc.), study logs (e.g. Drug Accountability Log, Site Visit Log, etc.).
- Well known about CTMS document tracking, push down to documents to country and site level, activity plan and export site visits report.
- Worked on systems like Siebel Clinical/CTMS, IVRS, eTMF, Preclears, Content server, pip, Medidata and metal wizard.
- Distribute the study Q&A / Directives log to project team and/or notify project team of where updated version can be located.
- Create and maintain a Task List for the study and continue to manage progress of the clinical administration deliverables.

Research Scholar
NIPER-Hyderabad (National Institute of Pharmaceutical Educational and Research)
Apr2014-Jun2015

- Data Mining and Article writing
- Experiment design & implementation
- Responsible for handling Cancer Cell lines
- Treatment of different cancer cell lines with different doses of Test drugs.
- Preparation and standardization of various handling methods.
- Finding out the most effective drug and its effective dose.
- Operating various instruments like Agarose Gel electrophoresis, Flow cytometer, electron Microscope etc.

EDUCATION

QUALIFICATION	UNIVERSITY	YEAR
Master of Pharmacy (Pharmacology)	NIPER Hyderabad	2015
Bachelor of Pharmacy	Faculty of Pharmacy, JNTU Anantapur	2013

AWARDS & CERTIFICATIONS

- Received Employee of the month twice in PPD, 2016
- GCP Certification From NIH and NIDA Clinical trials network

PROFESSIONAL APPOINTMENTS & MEMBERSHIPS

- Registered Pharmacist, Andhra Pradesh State Pharmacy council.

CONFERENCES, WORKSHOPS & CONTINUING EDUCATION

- Poster presentation on "Anti-microbial Multiple drug resistance in Tuberculosis"2013 NIPER-Hyderabad
- Poster presentation on "Anti-cancer effect of Andrographolide derivatives on Colon cancer"2014 NIPER- Hyderabad

Employee Sign & Date:

Vyshnavi Kure